M3476n

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service
Food and Drug Administration
SOUTHWEST REGION

Office of the Regional
Food and Drug Director
7920 Elmbrook Drive, Suite 102
Dallas, TX 75247-4982
TELEPHONE: 214-655-8100
FACSIMILE: 214-655-8130

WARNING LETTER

February 15, 2000

Certified Mail
Return Receipt Requested

00-SWR-WL-29/8

Ruthita Fike, CEO
Porter Hospital
2525 South Downing Street
Denver, CO 80210

Facility: Porter Breast Care
Denver, Colorado
Facility ID#: 131136

Dear Ms. Fike:

A representative from the Food and Drug Administration conducted an investigation at your facility on December 23, 1999 and found that your facility performed mammography after the September 22, 1999 expiration of its Food and Drug Administration (FDA) certificate. According to your facility records, the American College of Radiology (ACR) sent a letter dated August 19, 1999 to Stanley F. Smazal, Jr., M.D., stating that it denied your facility re-accreditation due to clinical image review (CIR) failure. During FDA's investigation at your facility, Ms. Jan Renicker, Coordinator of Porter Breast Care, stated that several communications occurred between your facility and ACR regarding submission of an acceptable corrective action plan while your facility continued performing mammography with an expired certificate.

Based on this investigation, it was determined that your facility operated without a valid FDA certificate from September 23, 1999 through October 25, 1999. The Mammography Quality Standards Act of 1992 (MQSA), under 42 U.S.C. 263(b)(1)(A), provides that no facility may conduct examinations or procedures involving mammography after October 1, 1994, unless the facility has a valid certificate.

Performing mammography without a valid certificate is a very serious violation of the law, which may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, assessing civil money penalties up to $10,000 or obtaining a court injunction against further mammography.

It is necessary for you to act on this matter immediately. Please inform this office in writing within fifteen (15) working day from the date you received this letter whether you have taken action regarding performing mammography without a valid certificate and how you plan to prevent this violation from recurring.

Please submit your response to:

Deborah M. McGee
Southwest Region Radiation Specialist
Food and Drug Administration
7920 Elmbrook Drive, Suite 102
Dallas, TX 75247
Telephone: 214-655-8100 x 138
Fax: 214-655-8130

Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter pertains only to the issue of the performance of mammography under a valid FDA MQSA certificate and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for mammography facilities by contacting the Mammography Quality Assurance Program, Food and Drug Administration, P.O. Box 6057, Columbia, MD 21045-6057 (1-800-838-7715) or through the Internet at http://www.fda.gov.

If you have more specific questions about mammography facility requirements or about the content of this letter, please feel free to contact Ms. McGee.

Sincerely yours,

Edward R. Esparza
Regional Food and Drug Director